

What is claimed is:

1. A method of treating a human cancer patient, said patient having undergone a malignant cell debulking procedure and being at risk for disease relapse due to a population of residual malignant cells that may remain viable in said patient following said debulking procedure, comprising:

a) providing a sample of stem cells from said patient, said sample being suitable for autologous transplantation into said patient;

b) performing an autologous transplant of said patient with said sample;

c) monitoring said patient until said patient is partially hematopoiesis recovered but is not fully immune-reconstituted;

d) administering to said patient an HLA-compatible, allogeneic peripheral blood leukocyte preparation having lymphocytes, in a regimen that causes a clinically significant graft-versus-malignant cell response; and

e) monitoring said patient for levels of malignant cells deriving from said population.

2. The method of claim 1, wherein said regimen comprises the following steps in sequence:

a) treating said patient by administration of about  $10^7$  cells/kg to about  $10^9$  cells/kg of HLA-compatible, allogeneic peripheral blood lymphocytes;

b) monitoring said patient for indications of a graft-versus-malignant cell response; and

c) if no or insufficient graft-versus-malignant cell response develops in said patient, escalating said treatment by performing at least one procedure selected from the group consisting of (1) administration of a number of HLA-compatible, allogeneic peripheral blood lymphocytes greater than the number of lymphocytes administered in step (a); (2) administration of a number of HLA-compatible, allogeneic peripheral blood lymphocytes at least as great as the number of lymphocytes administered in step (a), accompanied by administration of at least one T-cell-activating cytokine to said patient; (3) administration of HLA-compatible, allogeneic CAL's to said patient; and (4) administration of HLA-compatible, allogeneic CAL's, accompanied by administration in vivo of at least one T-cell-activating cytokine to said patient;

wherein more than one of said procedures is performed if no or insufficient graft-versus-malignant cell response develops in said patient following said first or subsequent procedure.

3. The method of claim 2, wherein step (a) further comprises administration in vivo of at least one T-cell-activating cytokine to said patient.

4. A method of treating a human cancer patient, said patient having undergone a malignant cell debulking procedure and being at risk for disease relapse due to a population of residual malignant cells that may remain viable in said patient following said debulking procedure, comprising:

a) providing a sample of stem cells from said patient, said sample being suitable for autologous transplantation into said patient;

b) performing an autologous transplant of said patient with said sample;

c) monitoring said patient until said patient is partially hematopoiesis recovered but is not fully immune-reconstituted;

d) administering to said patient an HLA-compatible, allogeneic peripheral blood leukocyte preparation having lymphocytes, in a regimen that causes a mild graft-versus-host response; and

e) monitoring said patient for levels of malignant cells deriving from said population.

1 5. The method of claim 4, wherein said regimen comprises the following  
2 steps in sequence:

3 a) treating said patient by administration of about  $10^7$   
4 cells/kg to about  $10^9$  cells/kg of HLA-compatible, allogeneic peripheral  
5 blood lymphocytes;

6 b) monitoring said patient for indications of a mild graft-  
7 versus-host response; and

8 c) if no or insufficient graft-versus-host response develops  
9 in said patient, escalating said treatment by performing at least one  
10 procedure selected from the group consisting of (1) administration of a  
11 number of HLA-compatible, allogeneic peripheral blood lymphocytes  
12 greater than the number of lymphocytes administered in step (a); (2)  
13 administration of a number of HLA-compatible, allogeneic peripheral  
14 blood lymphocytes at least as great as the number of lymphocytes  
15 administered in step (a), accompanied by administration of at least one  
16 T-cell-activating cytokine to said patient; (3) administration of HLA-  
17 compatible, allogeneic CAL's to said patient; and (4) administration of  
18 HLA-compatible, allogeneic CAL's, accompanied by administration of  
19 at least one T-cell-activating cytokine to said patient;

20 wherein more than one of said procedures is performed if no or  
21 insufficient graft-versus-host response develops in said patient  
22 following said first or subsequent procedure.

1 6. The method of claim 5, wherein step (a) further comprises  
2 administration in vivo of at least one T-cell-activating cytokine to said patient.

1 7. The method of claim 4, wherein said regimen comprises the following  
2 steps in sequence:

3 a) administering to said patient about  $10^7$  cells/kg to about  
4  $10^9$  cells/kg of HLA-compatible, allogeneic peripheral blood  
5 lymphocytes and at least one T-cell-activating cytokine to said patient;;

6 b) monitoring said patient for signs of a mild graft-versus-  
7 host response;

8 c) if no or insufficient graft-versus-host response develops  
9 in said patient, administering about  $10^7$  cells/kg to about  $10^9$  cells/kg of  
10 HLA-compatible, allogeneic CAL and at least one T-cell-activating  
11 cytokine to said patient; and

12 d) monitoring said patient for signs of a mild graft-versus-  
13 host response.

1 8. The method of claim 4, wherein said regimen comprises the following  
2 steps in sequence:

3 a) administering to said patient about  $10^5$  cells/kg to about  
4  $10^9$  cells/kg of HLA-compatible, allogeneic peripheral blood  
5 lymphocytes, said HLA-compatible, allogeneic peripheral blood  
6 lymphocytes comprising CAL, and at least one T-cell-activating  
7 cytokine to said patient;

8 b) monitoring said patient for signs of a mild graft-versus-  
9 host response;

10 c) if no or insufficient graft-versus-host response develops  
11 in said patient, administering about  $10^5$  cells/kg to about  $10^9$  cells/kg of  
12 HLA-compatible, allogeneic CAL and at least one T-cell-activating  
13 cytokine to said patient; and

14 d) monitoring said patient for signs of a mild graft-versus-  
15 host response.

1 9. The method of claim 2, 3, 5, 6, 7 or 8 wherein said cytokine is selected  
2 from the group consisting of IL2, IL4, IL5, IL6, IL7, IFN $\alpha$ , IFN $\gamma$  and TNF $\alpha$ .

1 10. The method of claim 4, wherein said stem cells are obtained from bone  
2 marrow.

1 11. The method of claim 4, wherein said stem cells are obtained from the  
2 peripheral circulation.

1 12. The method of claim 4, wherein said stem cells are obtained from fetal  
2 sources selected from the group consisting of fetal tissue, fetal circulation and  
3 umbilical cord blood.

1 13. The method of claim 4, wherein said malignant cells are leukemia  
2 cells.

1 14. The method of claim 4, wherein said malignant cells are lymphoma  
2 cells.

1 15. The method of claim 4, wherein said malignant cells are breast cancer  
2 cells.

1 16. The method of claim 1 or 4, wherein said HLA-compatible cells are  
2 fully HLA-matched with said patient.

1 17. The method of claim 1 or 4, wherein said HLA-compatible cells are at  
2 least haploidentical with said patient.

1 18. The method of claim 1 or 4, wherein said HLA-compatible cells are  
2 single HLA locus-mismatched cells from a sibling of said patient.

1 19. An article of manufacture comprising packaging material and a  
2 biological cell container within said packaging material, wherein said packaging  
3 material contains a label or package insert indicating that said biological cell  
4 container and any contents therein are to be used in the method of claim 1 or 4.